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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,940	07/07/2003	Cheryl R. Mitchell	590-004	9256

7590 08/03/2009
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EXAMINER

YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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08/03/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/614,940	Applicant(s) MITCHELL ET AL.	
	Examiner MICAH-PAUL YOUNG	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/7/03</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 7/07/03 was filed with the Specification on 7/7/03. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 10/125,367. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to compositions comprising electrolytes, carbohydrates and low water content. The formulation when concentrated has a Brix between 78-85, and water content below 5%. The formulation of the instant claims is broader than that of

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the '367 application in that the claims are silent to fiber, protein and starch hydrolysate content, however the instant claims are written with open claim language. The compositions of the '367 application would obviate the instant claims if allowed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13, 15, 17, and 19-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Takaichi et al (USPN 5,455,235 hereafter '235). The claims are drawn to a composition comprising liposomed electrolytes. The claims are drawn also drawn to a method for orally rehydrating a subject comprising drinking the oral rehydration solution.

The '235 patent teaches an oral formulation comprising liposomed electrolytes (abstract). The formulation comprises electrolytes such as magnesium potassium and calcium salts (col. 4, lin. 20-35). The liposome includes soybean phospholipid (col. 6, lin. 40-45). The formulation has an osmolality from 200-270 mOsmols (col. 4, lin. 10-19). The formulation further comprises vitamins, flavors and amino acids (col. 5, lin. 35-40). Vitamins include vitamin E, C and retinol (col. 5, lin. 51-55, col. 7, lin. 25-30), amino acids such as sodium glutamine, glycine (col. 5, lin. 38) and flavors include grapefruit, orange lemon and pineapple (co. 5, lin. 35). The water content of the formulation is about 0.8% in a concentrated form (col. 10, lin. 10-18). The

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formulation is rehydrated with an amount of water and delivered to the subject (col. 8, lin. 60-67). The ingredients are combined and homogenized in order to arrive at the concentrated form (col. 7, lin. 55-60).

These disclosures render the claims anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 10-12, 14, 16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Andon et al (USPN 5,468,506 hereafter '506). The claims are drawn to a composition comprising liposomed electrolytes and water, and a concentrated form of the composition.

The '506 patent discloses a composition comprising phospholipids, electrolytes, and a low concentration of water (abstract). The composition comprises phospholipids such as lecithin (col. 8, lin. 5) and electrolytes such as ionic calcium salts (col. 6, lin. 64-col. 7, lin. 13; col. 8, lin.

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8-65). The water content of the formulation can be kept low, below 20% (col. 11, lin. 65-col. 12, lin. 28). This low water content provides a viscous syrup comprising high fructose corn syrup having a Brix of 77 (col. 6, lin. 15-25). The formulation is homogenized (col. 11, lin. 65-col. 12, lin. 28).

The formulation differs from the instant claims in the water content. The '506 patent discloses a low water content of below 20%, while the instant claims have a water content below 10%. This is a result effective parameter that can be optimized through routine experimentation by those of ordinary skill in the art. The claims require the formulation to be concentrated, presumably removing the water content resulting in a viscous syrup with the resultant Brix value. The syrup of the '506 patent comprises a Brix of 77 and a low water content. It would have been prima facie obvious to lower the water content in order to further concentrate the syrup in order to reduce the size or increase the potency of the product. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various cosmetic compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

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With these things in mind it would have been obvious to optimize the concentrations of the water in order to increase the potency of the dehydrated syrup. One of ordinary skill in the art would have been motivated to optimize the water content with an expected result of a formulation useful as a drink or beverage base with a high potency that can be later diluted.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 7:00-4:30; every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618
/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618